GOVERNMENT OF INDIA
ATOMIC ENERGY
LOK SABHA

STARRED QUESTION NO:342
ANSWERED ON:07.08.2002
SAFETY NORMS OF NUCLEAR MEDICINE UNITS
SURESH KURUP

Will the Minister of ATOMIC ENERGY be pleased to state:

(a) whether an inspection conducted by the Atomic Energy Regulatory Board (AERB) in 35 nuclear medicine units in the country over the past two years has revealed that safety norms are being openly violated in all of them;

(b) if so, the details thereof; and

(c) the corrective steps taken/proposed to be taken in this regard?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF SMALL SCALE INDUSTRIES, MINISTER OF STATE IN THE MINIS PERSONNEL, PUBLIC GRIEVANCES AND PENSIONS, MINISTER OF STATE IN THE MINISTRY OF PLANNING AND M OF STATE IN THE DEPARTMENTS OF ATOMIC ENERGY AND SPACE (SHRIMATI VASUNDHARA RAJE)

(a) to A statement is laid on the Table of the House.

(b)

DEPARTMENT OF ATOMIC ENERGY

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO.342 FOR ANSWER ON 7.8.2002 BY SURESH KURUP REGARDING SAFETY NORMS OF NUCLEAR MEDICINE UNITS

(a) & (b) As a part of its regular programme, the Atomic Energy Regulatory Board (AERB) carried out regulatory inspection in 35 nuclear medicine units located in different parts of the country. The overall safety status of these facilities was satisfactory. However, the inspections revealed a few safety violations in many of the institutions. These included improper storage of radioactive materials, procedural lapses, poor work practices and deficiencies in the layout of the facilities etc. which are not hazardous or fatal but unhygienic and avoidable.

(c) Based on the inspection reports, AERB issued show cause notices to the owners of the erring installations before enforcing regulatory restrictions. The restrictions included suspension of practices for different periods and indefinite stoppage of the practice in one instance. The institutions were allowed to restart work only after the required remedial measures were implemented. AERB sent reports stating the deficiencies observed to each installation. The information on the violations would be discussed at the conferences and workshops organised by nuclear medicine professionals to bring about general awareness among them. This would help to improve the safety status in nuclear medicine units all over the country.

DEPARTMENT OF ATOMIC ENERGY

NOTE FOR SUPPLEMENTARIES

LOK SABHA STARRED QUESTION NO. 342 FOR ANSWER ON AUGUST 7, 2002 REGARDING NUCLEAR MEDICINE UN SHRI SURESH KURUP.

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PART - I

EXECUTIVE SUMMARY

The question appears to have been asked in the background of a newspaper report (The Times of India, April 25, 2002, Mumbai edition) on the safety status of nuclear medicine facilities in India. The report referred to the inspections carried out by the staff of the Atomic Energy Regulatory Board (AERB) and the violations of safety provisions in the nuclear medicine facilities.

The Atomic Energy Regulatory Board which is empowered to enforce radiological safety provisions in all radiation installations in the country monitors the safety status by scrutinizing the reports received from the institutions, by reviewing the radiation doses received by radiation workers and by carrying out periodic safety inspections. The staff of AERB inspect medical, industrial and research institutions using radiation sources. Medical institutions include nuclear medicine centres where prescribed quantities of radioisotopes are administered to patients for diagnosis and therapy.

Over a period of just over two years AERB inspected 35 nuclear medicine facilities.The overall status of radiological safety in these facilities was satisfactory. However, inspections revealed a few violations such as improper storage of radioactive materials, procedural lapses, poor work practices and deficiencies in the layout of the facilities. AERB initiated regulatory actions including suspension of practices for different periods and indefinite stoppage of the practice in one instance. AERB allowed the institutions to restart and work only after they implemented required remedial measures.

PART - II

INFORMATION IN DETAIL

Nuclear medicine is a specialised branch of medicine, in which radioisotopes such as technitium-99m and iodine-131 are administered to patients for diagnosis and treatment. There are at present 126 Nuclear medicine centres in the country employing 160 approved nuclear medicine physicians and 220 technologists. During the regulatory inspections, the inspection team from AERB examines whether the institutions comply with the safety provisions stipulated in the following Rules, Surveillance Procedures and Code.

1) Radiation Protection Rules, 1971 Published in Part II, Section 3
(i) The Gazette of India, October 30, 1971. 2) Radiation Surveillance Procedures for Medical Application of Radiation, 1989 Published in Part II, Section 3(I) The Gazette of India. 3) AERB Safety Code on Nuclear Medicine Facilities, 2001 (Revision-1).

As a part of this important regulatory function, AERB staff inspected thirty-five nuclear medicine laboratories out of about 126 institutions over a period of just more than two years. The overall safety status of these facilities was satisfactory. However, the inspection revealed a few violations in many of the institutions. These included improper storage of radioactive materials, procedural lapses, poor work practices and deficiencies in the layout of the facilities.

When AERB issues authorisation to an institution it approves the layout of the treatment room by taking aspects of radiological protection into consideration. In some instances, the institution shifted the location of the facility to a site not approved by AERB ignoring requirements of radiological protection.

When patients are treated with high doses of radioisotopes such as iodine-131 they are required to be kept in isolation for a few days. Isolation was inadequate in some instances. This leads to unnecessary radiation exposure to other individuals. Though the magnitude of such radiation exposures are low, they are not justifiable.

All nuclear medicine centres are required to own functioning radiation measuring instruments. The AERB inspection team noted that the instruments were not functioning in some institutions. This is because they were not calibrated properly or were operating with run-down batteries. This deficiency may lead to the institution releasing patients before the activity in their body decays down to the limit prescribed by AERB.

Though the violations are not major, AERB has initiated appropriate follow up measures to ensure that corrective steps are taken by the erring institutions. AERB imposed regulatory restrictions against some of the institutions.AERB staff pointed out the deficiencies, issued show cause notices to the defaulting institutions and directed them to comply with the relevant safety provisions. The regulatory action included the suspension of the practices for different periods till safety stipulations are complied with and indefinite stoppage of practice in one instance. The institutions were allowed to function only after they complied with the safety stipulations.

The radiological consequences due to the violations are not serious as the amount of radioactivity handled is small. One of the basic principles of radiological protection is that all radiation exposures must be justified, needless exposures should be avoided totally and radiation exposures to patients shall be minimum consistent with clinical requirements. The emphasis is to ensure that radiation doses to workers and patients are kept at values As Low As Reasonably Achievable (ALARA)Any nuclear medicine facility can achieve this objective by complying with the AERB safety stipulations in letter and spirit.

AERB informed the concerned institutions about the deficiencies observed and directed them to initiate remedial measures.As is the accepted practice, a committee constituted by AERB reviewed the inspection reports and recommended appropriate enforcement actions on defaulting institutions. In three instances, the nuclear medicine practice was suspended for three months. In one instance, the authorisation to use radioisotope was withdrawn indefinitely as the institution did not fulfill essential requirements such as availability of qualified staff and proper patient isolation facility.

If the institutions do not employ adequately qualified technologists, AERB permits them to operate nuclear medicine facilities only if the radioisotopes are handled by an authorised nuclear medicine physician. There were instances in which under-qualified technologists were found to handle radioisotopes. One of the reasons may be the paucity of trained manpower. Taking this factor into account, AERB initiated steps to recognise more institutions to conduct courses to train technologists.AERB plans to conduct short term courses in different parts of the country to train technologists to handle radioisotopes safely. One such course was held in Mumbai.

Improper storage of radioactive material results in unnecessary increase in radiation levels in the facility. Nuclear medicine facility is required to have foot operated waste bins, tables with smooth impervious surfaces which assist ease of decontamination if any spillage occurs. Such deficiencies were noted in a few facilities.

PART - III

POSSIBLE SUPPLEMENTARY QUESTIONS ALONG WITH ANSWERS

Que.1 What is the status of Nuclear Medicine Practices in India?

Ans. Nuclear medicine practices in India started several decades ago.During the early years, the expertise and equipment were available only in a few institutions. The equipment available was limited to a few indigenously developed scanners and thyroid uptake probes. Currently about 160 nuclear medicine physicians supported by nearly 220 nuclear medicine technologists are practising this branch of medicine in 126 (as on date) institutions located in different parts of the country. The type and variety of practices have registered significant growth over the past few years. Annually about 15 to 20 qualified nuclear medicine physicians are entering the field. Advanced facilities to carry out most of the clinical investigations exist in the country.

Que.2 What are the safety violations observed by AERB?

Ans. The inspection teams from AERB observed safety violations such as improper storage of radioactive materials, procedural lapses, poor work practices and deficiencies in the lay out of the facilities.

Que.3 What are the consequences of the violations?

Ans. The radiological consequences of the violations are not serious, as the amounts of radioactivity handled are small. The violations may result in small but needless radiation exposures to radiation workers and members of the public. Though small radiation exposure may entail only low risk, according to the basic principles of radiological protection all needless exposures are to be avoided. Persons need not accept the risk as it is not justifiable.

Que.4 If the radiological risks from violations are small, why is AERB taking action against defaulting institutions?

Ans. Some of the violations may cause small radiation exposures to workers and members of the public. According to the basic principles of radiological protection all needless exposures must be avoided altogether. Unavoidable radiation exposures to workers and patients should be As Low As Reasonably Achievable (ALARA) consistent with clinical requirements.This is called the ALARA principle. AERB desires to enforce radiological safety provisions in letter and spirit to achieve the objective of ALARA principle.The aim of AERB is to achieve excellence in safety performance of all radiation installations.

Que.5 What is the nature and type of actions taken by AERB?

Ans. AERB issued show cause notices to the owners of the erring installations before enforcing regulatory restrictions.The restrictions included suspension of practices for different periods and indefinite stoppage of the practice in one instance. The institutions were allowed to restart work only after the stipulated remedial measures were implemented.

Que.6. Whether the remedial measures suggested were implemented?

Ans. Yes Sir. AERB has received letters from the nuclear medicine units that they have implemented the remedial measures.AERB re-inspected some of the institutions and confirmed their compliance.

Que.7. On what basis are the institutions selected for inspection?

Ans. AERB Inspects radiation installations prior to their commissioning.AERB reviews inputs such as periodic reports from the institutions, radiation dose records of workers and reports of unusual incidents. These inputs help in selecting institutions for inspection.

Que.8 What are the future regulatory activities of AERB in the area of nuclear medicine?

Ans. AERB has augmented the frequency of inspections.The pace of this activity will be maintained. A closer watch will be maintained on the prompt receipt of the reports of safety status from various nuclear medicine units. Such reports will be scrutinised to identify institutions which merit detailed monitoring.

General information on regulatory inspections, the observed violations and proposed remedial steps will be brought to the notice of all nuclear medicine facilities. Details of violations and remedial measures will be highlighted to show that excellence in safety performance can be achieved at little cost.

PART - IV

Nuclear Medicine Institutions Inspected During the Years 2000-2002 (as on date)

1. Victoria Hospital, Bangalore.

2. Elbit International Medical centre, Bangalore

3. Kidwai Memorial Institute of Oncology, Bangalore

4. Manipal Hospital, Bangalore

5. Bangalore Institute of Oncology, Bangalore

6. Sri Sathya Sai Institute of Higher Medical education, Bangalore

7 Government Arignar Anna Memorial Cancer Hospital, Kancheepuram

8. Sri. Narayana Hrudayalaya, Bangalore

9. Sri Ramachandra Medical College & Research Centre, Chennai

10. Christian Medical College, Vellore

11. Meenakshi Mission Hospital, Madurai

12. Malar Hospital, Chennai

13. Cancer Institute, Adyar, Chennai

14. Vijaya Health Centre, Chennai

15. Madras Medical Mission, Chennai

16. Apollo Hospital, Chennai

17. KJ Hospital, Chennai

18. SN Medical College, Agra

19. MD Oswal Cancer Treatment & Res.Centre, Ludhiana

20. PD Institute of Nuclear Medicine, Amritsar

21. Pace Imaging Centre, Amritsar

22. Soin Diagnostic Centre, Ludhiana

23. Fortis Heart Institute, Chandigarh

24. JLN Hospital & Research Centre, Bhilai

25. BSR cancer Hospital, Bhilai

26. International Institute of Neuro Sciences & Oncology, (INSCOL), Chandigarh

27. PGI, Chandigarh

28. Medwin Hospital, Hyderabad

29. Nizam`s Institute of Medical Sciences, Hyderabad

30. Apollo Hospital, Hyderabad

31. MNJ Cancer Institute, Hyderabad

32. Vijaya Diagnostics Centre, Hyderabad

33. PD Hinduja National Hospital, Mumbai

34. Jaslok Hospital, Mumbai

35. Spectrum Nuclear Medicine Centre, Mumbai.

PART - V

NUCLEAR MEDICINE CENTRES IN KERALA

1. Regional Cancer Centre, Thiruvananthapuram

2. Modern Imaging Centre, Kottayam

3. Amrita Institute of Medical Sciences & Research Centre, Kochi

4. Cochin Diagnostic Research Centre, Kochi

PART - VI

NUCLEAR MEDICINE CENTRES - STATE WISE

1. Andhra Pradesh 12

2. Assam 1

3. Bihar 4

4. Delhi 12

5. Gujarat 4

6. Himachal Pradesh 1

7 Haryana 3

8. J&K 1

9. Kerala 4

10. Karnataka 12

11. Maharashtra 23 (Mumbai-14)

12. Madhya Pradesh 7

13. Orrisa 3

14. Punjab 6

15. Pondicherry 2

16. Rajasthan 4

17. Tamil Nadu 15

18. UP 3

19. West Bengal 9
Total 126.